

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NOVARTIS CORPORATION and
NOVARTIS PHARMACEUTICALS
CORPORATION,

Plaintiffs,

v.

TEVA PARENTERAL MEDICINES, INC.,
TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICAL INDUSTRIES LTD.,

Defendants.

Civil Action No. 08-952-SLR

**TEVA PARENTERAL MEDICINES, INC.'S
ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Teva Parenteral Medicines, Inc. ("TPM") hereby answers the Complaint ("the Complaint") filed by Novartis Corporation and Novartis Pharmaceuticals Corporation (collectively "Novartis") as follows:

Nature of the Action

1. To the extent that paragraph 1 makes allegations directed to Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), or states conclusions of law, no response is required from TPM. To the extent that paragraph 1 makes allegations directed to TPM, TPM admits that it filed ANDA No. 90-823 and that Novartis purports to bring this action under the patent laws of the United States. TPM denies the remaining allegations in paragraph 1.

Related Action

2. To the extent that paragraph 2 makes allegations directed to Teva USA and Teva Ltd., or states conclusions of law, no response is required from TPM. To the extent that paragraph 2 makes allegations directed to TPM, TPM admits that Civil Action No. 08-459-SLR is currently pending before this Court, involves the same patent being asserted in this action, and relates to ANDA Nos. 78-576 and 78-580 for zoledronic acid IV (infusion) Eq. 4mg base/5ml (poly and glass vials) filed by TPM. TPM denies the remaining allegations in paragraph 2.

Parties

3. On information and belief, TPM admits the allegations in paragraph 3.
4. On information and belief, TPM admits the allegations in paragraph 4.
5. TPM is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 and denies the same.
6. TPM is an indirect wholly-owned subsidiary of Teva USA. TPM is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 19 Hughes, Irvine, California. TPM denies the remaining allegations in paragraph 6.
7. Paragraph 7 makes allegations as to Teva USA only, and thus no response is required from TPM.
8. Paragraph 8 makes allegations as to Teva Ltd. only, and thus no response is required from TPM.
9. To the extent that paragraph 9 makes allegations directed to Teva USA and Teva Ltd., no response is required from TPM. To the extent that paragraph 9 makes allegations directed to TPM, TPM admits that it prepared and submitted ANDA No. 90-823, and that it

manufactures some generic pharmaceuticals. TPM denies the remaining allegations in paragraph 9.

Jurisdiction and Venue

10. To the extent that paragraph 10 makes allegations directed to Teva USA and Teva Ltd., no response is required from TPM. To the extent that paragraph 10 makes allegations directed to TPM, TPM admits that Novartis purports to bring this action under the United States Patent Laws, and admits that Novartis purports to base jurisdiction over the subject matter pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201 and 2202. TPM denies the remaining allegations in paragraph 10.

11. To the extent that paragraph 11 makes allegations directed to Teva USA and Teva Ltd., no response is required from TPM. To the extent that paragraph 11 makes allegations directed to TPM, for purposes of this case only, TPM admits that this Court has personal jurisdiction over TPM. TPM denies the remaining allegations in paragraph 11.

12. To the extent that paragraph 12 makes allegations directed to Teva USA and Teva Ltd., no response is required from TPM. To the extent that paragraph 12 makes allegations directed to TPM, for purposes of this case only, TPM admits that venue with respect to TPM is proper in this judicial district. TPM denies the remaining allegations in paragraph 12.

Novartis's '130 Patent

13. TPM admits that on its face the '130 patent states that it is entitled "Substituted Alkanediphosphonic Acids and Pharmaceutical Use," identifies the issue date as July 3, 1990, and identifies the inventors as Knut A. Jaeggi and Leo Wilder. TPM further admits that a copy of the '130 patent is attached to the Complaint. TPM denies the remaining allegations in paragraph 13.

14. On information and belief, TPM admits that Novartis markets commercial formulations of zoledronic acid under the trade names Zometa[®] and Reclast[®]. TPM further admits that the FDA's website identifies "Novartis" as the company that submitted NDA 21-223 and 21-386 for Zometa[®]. TPM further admits that the FDA's website identifies "Novartis" as the company that submitted NDA 21-817 for Reclast[®] and "Novartis Pharms" as the company that submitted NDA 22-080 for Reclast[®]. TPM further admits that the Orange Book lists the '130 patent with respect to both Zometa[®] and Reclast[®]. TPM denies the remaining allegations in paragraph 14.

Teva's Notice Letter and ANDA Filing

15. To the extent that paragraph 15 makes allegations directed to Teva USA and Teva Ltd., no response is required from TPM. To the extent that paragraph 15 makes allegations directed to TPM, TPM admits that TPM's Notice Letter is dated November 7, 2008, and further states that such Notice Letter speaks for itself. TPM denies the remaining allegations in paragraph 15.

16. To the extent that paragraph 16 makes allegations directed to Teva USA and Teva Ltd., no response is required from TPM. To the extent that paragraph 16 makes allegations directed to TPM, TPM states that its Notice Letter speaks for itself. TPM denies the remaining allegations in paragraph 16.

17. To the extent that paragraph 17 makes allegations directed to Teva USA and Teva Ltd., or states conclusions of law, no response is required from TPM. To the extent that paragraph 17 makes allegations directed to TPM, TPM is informed and believes that this action was commenced before the expiration of forty-five days from the date Novartis received the TPM Notice Letter. TPM denies the remaining allegations in paragraph 17.

Count I: Infringement of United States Patent No. 4,939,130

18. TPM repeats and incorporates herein by reference its responses to paragraphs 1-17.

19. To the extent that paragraph 19 makes allegations directed to Teva USA and Teva Ltd., no response is required from TPM. To the extent that paragraph 19 makes allegations directed to TPM, TPM denies the same.

20. To the extent that paragraph 20 makes allegations directed to Teva USA and Teva Ltd., no response is required from TPM. To the extent that paragraph 20 makes allegations directed to TPM, TPM denies the same.

21. To the extent that paragraph 21 makes allegations directed to Teva USA and Teva Ltd., no response is required from TPM. To the extent that paragraph 21 makes allegations directed to TPM, TPM denies the same.

TPM further answers that any allegations in the Complaint requiring a response from TPM not specifically admitted are denied. TPM also denies that Novartis is entitled to the judgment and relief prayed for in paragraphs (a)-(h) of the Complaint.

TPM'S AFFIRMATIVE DEFENSES

First Affirmative Defense: Non-Infringement

The manufacture, use, offer for sale, sale or importation of TPM's Zoledronic Acid Injection specified in ANDA No. 90-823 does not and will not infringe any valid and enforceable claim of the '130 patent, either literally or under the doctrine of equivalents.

Second Affirmative Defense: Invalidity

The claims of the '130 patent are invalid under 35 U.S.C. §§ 101 *et seq.*

TPM specifically reserves the right to assert each and every other defense which may become evident in the course of discovery, including but not limited to inequitable conduct.

WHEREFORE, TPM prays that the Court enter judgment against Novartis and in favor of TPM, dismissing with prejudice each of the claims asserted by Novartis, and that the Court award TPM any other relief it deems to be just and proper.

January 7, 2009

BAYARD, P.A.

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CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on January 7, 2009, he served the foregoing documents by email and by hand upon the following counsel:

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The undersigned counsel further certifies that, on January 7, 2009, he served the foregoing documents by email and by U.S. Mail upon the following counsel:

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